

# Announcement Request for Applications HLT-01-92 Biomarkers of Toxic Pollutants in Human Health

## **Background**

The U.S. Environmental Protection Agency (EPA) is responsible for protecting public health from the adverse effects of exposures to environmental agents. In developing regulations to protect public health, EPA currently relies on quantitative assessments of health risks associated with different pollutants. However, the current lack of understanding about the underlying biological, chemical, and physical processes that constitute exposure and its effects also limits EPA's ability to accurately assess exposure.

The Office of Research and Development (ORD), the research arm of EPA, has published a research strategy document entitled "ORD Health Biomarkers Program" (EPA/600/9-91/009, April 1991). This document contains research plans that include development of biomarkers, validation of markers, monitoring of populations, and development of quantitative risk assessment methods. Consistent with this plan, ORD's Office of Exploratory Research issues this *Request for Applications (RFA)* to address *only* the development of biomarkers for exposure and effects related to adverse human health conditions.

### Scope

The purpose of this RFA is to implement Phase One of ORD's research strategy by supporting research on the identification and development of new and potentially useful biological markers of exposure and effects applicable to human health. The primary criteria for human biomarkers are to provide practical tests, and a higher priority will be given to markers which are:

- measurable in human breath, fluids, or tissues
- · measurable using minimal or non-invasive techniques
- interpretable in terms of human susceptibility to exposure or effect
- indicative of a significant and adverse health effect rather than minor or potential conditions.

The areas of consideration for this RFA include only neurotoxicology, reproductive and developmental toxicology, immunotoxicology, pulmonary toxicology, organ toxicology, and genetic (non-cancer) toxicology. The biomarkers may occur as behavioral endpoints, or at the organ, cellular, or molecular levels. Although the use of whole organisms may be necessary in some instances, studies involving cellular, biochemical, and genetic processes are particularly encouraged.

# **Exclusions and Limitations**

This RFA particularly excludes cancer research, epidemiology, and clinical studies. These topics are likely to be the subjects of future RFAs. Although priority pollutants (Clean Water Act) were mentioned in the pre-announcement, pollutants related to the Clean Air Act, Toxic Substances Control Act, and the Federal Insecticide, Fungicide, and Rodenticide Act are all acceptable under this RFA announcement.

### **Mechanisms of Support**

Assistance under this RFA will be provided by a research grant administered through EPA's research grants program. The applicant will be responsible for planning, directing, and executing the proposed research. Support under this program is limited to nonprofit research organizations and educational institutions.

Approximately \$1.6 million will be available from fiscal 1992 funds, and it is estimated that about 10 to 12 projects will be supported. Each project will be supported for a period of up to 3 years at approximately \$100,000 per year. This RFA is for a double competition with closing dates of April 15, 1992, and October 15, 1992.

### The Application

Each application will consist of the APPLICATION FOR FEDERAL ASSISTANCE FORM (Standard Forms 424 and 424A) and separate sheets providing the budget breakdown for each year of the project, curriculum vitae for the principal investigators, abstract of the proposed project, and a project narrative. All certification (drug-free workplace, etc.) forms must be signed and included with the application. Application forms, instructions, and other pertinent information are contained in the federal grant application kit obtainable from:

Research Grants Staff (RD-675) U.S. Environmental Protection Agency 401 M Street, SW Washington, DC 20460

# **Special Instructions**

- The project narrative section of the application must not exceed twenty-five 8 1/2 x 11 inch, consecutively numbered pages of standard type (10 characters per inch), including tables, graphs, and figures. Attachments, appendices, and reference lists for the narrative section may be included but come under the 25-page limitation. The SF-424 and other forms, itemized budget, resumes, and the abstract are not included in the 25-page limitation.
- Biographical sketches or resumes must not exceed two pages for each principal investigator and should focus on education, position held, and most recent or related publication.
- 3. Project periods will be for a maximum of three years.
- 4. Applications in response to this RFA must be identified by printing "RFA HLT-01-92" in Item 10 on the face page of Form 424 or in Item 3 of the old Form 5700-12. The absence of the above identifier from an application absolves EPA of any responsibility if it is not reviewed along with the other applications responding to the RFA.

# **Application Review**

All applications will be reviewed at a single meeting, after the closing date, by a scientific peer review panel that will evaluate and rank each proposal according to its scientific merit as a basis for recommending Agency approval. The panel will consider:

- the quality of research plan including theoretical or experimental design, originality, and creativity
- the qualifications of the research team
- · the availability and adequacy of facilities and equipment
- · the appropriateness of the proposed budget.

# **Application Submission**

To be considered, the original and eight copies of the application must be received no later than the close of business on the respective closing dates. The applications must be sent to:

Grants Operations Branch (PM-216F) Grants Administration Division U.S. Environmental Protection Agency 401 M Street, SW Washington, DC 20460

For overnight express mail, the address is:

Grants Operations Branch (202)260-9266 Grants Administration Division U.S. Environmental Protection Agency 499 South Capital Street, SW Washington, DC 20460

## **Staff Contact**

Questions relating to this solicitation may be directed to Clyde Bishop on (202) 260-7473.

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